



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,007	05/02/2007	Mitsuharu Miwa	46884-5479	7737

55694 7590 04/28/2011
DRINKER BIDDLE & REATH (DC)
1500 K STREET, N.W.
SUITE 1100
WASHINGTON, DC 20005-1209

EXAMINER

BRUTUS, JOEL F

ART UNIT	PAPER NUMBER
----------	--------------

3777

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

04/28/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBRIPDocket@dbr.com
penelope.mongelluzzo@dbr.com

Office Action Summary	Application No. 10/580,007	Applicant(s) MIWA ET AL.	
	Examiner JOEL F. BRUTUS	Art Unit 3777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/3/11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-2, and 4-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 1, line 12, the following limitation is not supported in the disclosure: "as a single image". Applicant disclose in paragraph 0050 that normal and fluorescence images are overlapped [see 0050. disclosure] but fails to disclose the images are acquired as a single image as claimed.

Regarding claims 2, 4-8, they are rejected for the same reason as set forth above because they depend on claim 1.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi (Pub. No.: US 2002/0013531) in view of Sekiguchi (US Pat: 4,821,117) and further in view of Konomura et al (US Pat: 5,697,885).

Regarding claims 1-2, Hayashi teaches a sentinel lymph node detection system that anticipates the claimed invention. Hayashi teaches a near infrared fluorescent colorant indocyanine green is locally injected in advance into the vicinity of a tumor [see 0059, 0101]; and the fluorescent light emitted from the area of tissue under examination upon irradiation thereof by stimulating light is observed by use of a goggle type observation unit and detection of the sentinel lymph node is performed [see 0059].

Hayashi further teaches a fluorescent lamp and a stimulating light projecting unit which provided with a light source for producing fluorescent image observation using near infrared stimulating light [see 0060]; the lamp emits white light as illuminating light composed of visible light [see 0061]; the stimulating light is provided with a semiconductor laser for producing stimulating light having a wavelength of 790 nm and a light source driver [see 0062]. Hayashi teaches an observation unit comprises an objective lens, a near infrared cutoff filter having a wavelength of 700 nm or larger and another near infrared cutoff filter cuts off light having a wavelength of 820 nm or smaller [see 0064]; a photographing unit (image pick up means) [see 0080-84] and a monitor for displaying images [see 0100].

With regards to adjusting means; Applicant discloses adjusting a luminance of contrast of an image [see 0035]. Accordingly, Hayashi teaches a signal processing circuit 241 for performing sampling, amplifying and clamping [see 0085]

Art Unit: 3777

which are image signal contrast and circuit 241 therefore is used as an adjusting means (emphasis added) and further disclose a signal processing circuit 231 to separate luminescence and color signals [see 0093].

Hayashi may not mention normal and florescence images are overlapped and obtained as a single image.

Nonetheless, Sekiguchi teaches visible radiation image and the fluorescent image are simultaneously displayed or overlapped on the display unit 41 [see column 4 lines 23-25, lines 28-43 and fig 3].

In addition, Konomura et al disclose in the publication of Japanese patent application laid open No.57784/1985 is disclosed an apparatus to overlap the visible image and infrared image taken at the same time [see column 2 lines 10-16]

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Hayashi with Sekiguchi and Konomura et al by acquiring overlapped visible and infrared image at the same time or as a single; in order to easily and securely identify an affected part of the internal organ [see column 1 lines 60-61 of Sekiguchi].

Regarding claim 4, Hayashi teaches the observation unit comprises an eyepiece [see 0063] (eyepieces are made to be mounted on a head portion of an observer).

Regarding claim 5, Hayashi teaches a fluorescent image memory for saving the digitized color image signal, a D/A conversion circuit, A/D conversion circuit [see 0085, 0094-996].

Regarding claim 6, Hayashi also teaches observation means consisting of a variety of optical means, a normal image optical path, and optical system for focusing [see 0078]. The sentinel lymph node is implemented in laparoscope comprises an insertion portion, an illumination unit, a photographing unit [see 0080-84]; the insertion portion comprises a light guide [see 0082].

Regarding claims 7-8, Hayashi doesn't teach reflection image at light intensity no more than fluorescence intensity of fluorescence image and nod no more than 10%.

However, Sekiguchi teaches visible radiation image/fluorescence intensity contour lines displaying switch 47 which instructs to display a visible radiation image and fluorescent image and fluorescent intensity contour lines to be overlapped each other [see column 4 lines 33-43]. It shows that light intensity of visible image and fluorescence image can be set through switch 47 (emphasis added)

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine Hayashi with Sekiguchi; in order to use intensity as desired such as no more than 10% of the fluorescence image intensity.

Response to Arguments

5. Applicant's arguments with respect to claims 1-2, 4-8 have been considered but are moot in view of the new ground(s) of rejection.

Regarding the 112 rejection, Applicant's amendment doesn't overcome the rejection because Applicant disclose in paragraph 0050 that normal and fluorescence images are overlapped [see 0050. disclosure] but fails to disclose the images are acquired as a single image as claimed.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tse Chen can be reached on (571)272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777